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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 5-22-02
Publication Date 5-23-02
Certifier A. Corbin

Food and Drug Administration

[Docket No. 01P–0447]

02 MAY 21 P3:13

Determination That Ardeparin Sodium Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that ardeparin sodium injection (Normiflo) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ardeparin sodium injection.

FOR FURTHER INFORMATION CONTACT: David Read, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5605.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data

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to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

Ardeparin sodium injection (Normiflo) was the subject of approved NDA 20–227, formerly held by Wyeth-Ayerst and then by Pharmacia & Upjohn. Normiflo is a low molecular weight heparin indicated for the prevention of deep vein thrombosis which may lead to pulmonary embolism following knee replacement surgery. FDA received a request from Pharmacia & Upjohn, dated May 22, 2001, to withdraw approval of NDA 20–227 for Normiflo injection in accordance with 21 CFR 314.150(c). Following Pharmacia & Upjohn's request, Normiflo was moved from the prescription drug product list to the "Discontinued Drug Product List" section of the Orange Book. Approval of the application was withdrawn on February 11, 2002 (67 FR 6264).

In a citizen petition dated September 19, 2001 (Docket No. 01P–0447/CP1), submitted under 21 CFR 10.30, John W. Herr requested that the agency determine whether ardeparin sodium injection was withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Normiflo was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that Normiflo was withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data for possible postmarketing adverse event reports, but has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined in this notice, ardeparin sodium injection approved under NDA 20–227 was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list Normiflo (ardeparin sodium injection) in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing

for reasons other than safety or effectiveness. ANDAs that refer to Normiflo (ardeparin sodium injection) may be approved by the agency.

Dated: 5/15/02
May 15, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

BILLING CODE 4160–01–S